GUIDANT

November 29, 1999

Dockets Management Branch
HFA-305
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Subject: Comments on the Least Burdensome Draft Guidance
Docket No. 99D-2873

Dear Sir or Madam:

Enclosed are the comments from Guidant Corporation concerning the Draft Guidance for Industry and FDA Reviewers on *"Evidence Models for the Least Burdensome Means to Market"*.

In addition to the comments provided below, Guidant Corporation concurs with the comments submitted on behalf of industry by the various Industry trade associations such as HIMA, MDMA, NEMA, AMDM, JCIM, MassMEDIC, IMDMC, and Medical Alley.

Here follows Guidant Corporations comments to the Least Burdensome Guidance:

1. QUESTION **1,** PAGE 5;

Under *Points to consider* section *Our current knowledge of the interaction of the disease/condition and the product,* a key missing component of this guidance is consideration of "valid medical practice" that could be provided by a physician panel in terms of the need for clinical study and the most appropriate data to gather.

2. QUESTION **1,** PAGE 5;

When evaluating a new device against a predicate device, the guidance should provide more specific definitions and examples of when the use of a historical control (predicate device) or "objective performance criteria" (OPC) to study a device rather than Randomized Controlled Trial (RCT).

3. QUESTION **1,** PAGE 6;

Under *Points to Consider* section *Relevance and applicability of the clinical* data. the Guidance document and the agency should recognize the advances in technology regarding the laboratory testing (bench testing) of devices. In many cases bench testing is more appropriate than human testing as many programming parameters can be

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evaluated whereas it may not be appropriate or necessary to subject a patient to so many programming iterations.

4. QUESTION 2, PAGE 7;

When answering Question 2, FDA should consider using an approach of "revolutionary" vs. "evolutionary" device design as a framework for the FDA and industry to refer to in characterizing new devices and therapies for least burdensome clinical requirements. One example of a revolutionary device using current criteria would be the intent to design a device for a new medical indication. The need for clinical data is likely appropriate in this case. An example of an evolutionary device design would be represented by the next iteration of a pacemaker that added some diagnostic and minor therapy features to an already market approved device. These types of product evolutions do not generally involve any new technology rather they represent enhancements to existing product functionality. Evolutionary device designs are necessary for the industry to advance the science and development of new devices and therapies as it provides for the post market experience for use in designing future devices.

5. QUESTION 2 PAGE 9;

Under *Other considerations* section *The method of analysis and reporting,* the guidance should provide more information and examples of statistical methods and models to consider when designing a study. Many of the FDA's questions and concerns that are expressed about clinical designs revolve around the statistics used. This approach is consistent with the "scientific basis" that FDA has identified as necessary to the design of clinical trials.

Respectfully Submitted,

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